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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,132	08/28/2006	Patrice Richard	Q94512	8183

23373 7590 09/01/2009

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EXAMINER	
SU, SUSAN SHAN	
ART UNIT	**PAPER NUMBER**
3761	
MAIL DATE	**DELIVERY MODE**
09/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,132	RICHARD, PATRICE	
	Examiner	Art Unit	
	SUSAN SU	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-19 are pending wherein Claims 1-8 are amended and Claims 11-19 are new. All claims are examined on the merits.

Response to Arguments

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Specifically, Applicant argues that since Seddon teaches a system for use in wound drainage and Deverre teaches placental blood extraction by gravity, the Examiner has failed to provide evidence that it would be obvious for one skilled in the art to combine the two distinct apparatuses that are designed to be used in different applications. The Examiner finds this argument persuasive.

However, the Examiner disagrees with Applicant's argument that one would not combine Seddon's vacuum bottle to the extraction of blood because Seddon teaches a passive system. The application of vacuum to a body part constitutes an active action (versus the use of gravity, which would be passive), thus making the Seddon system an active fluid removal system. Applicant also argues that an "accelerating" fluid withdrawal effect does not exist in the normal usage of Seddon's vacuum bottles. The Examiner respectfully disagrees. Suction would necessarily result in quicker removal of a fluid when compared to a system that does not use suction, such as that of Deverre, which employs only the force of gravity for drawing blood out of the placenta. Therefore, when one wishes to withdraw more blood from the placenta in a given time

period, then it is obvious to use vacuum, regardless of whether the suction is generated from a pump, a syringe, a bottle, or other suction means.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3-7, 9, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deverre (US 7,131,958) in view of Dracker (US 5,356,373).

With regard to Claim 1, Deverre teaches a placental-blood extraction device comprising at least one extraction needle (4 or 5) for piercing the vein of the umbilical cord or of the placenta, a collection vessel (1) connected to said at least one needle via at least one tube (2). However, Deverre does not teach suction means connected to said at least one needle. Dracker teaches using suction means (Col. 4 lines 45-53) connected to a needle for sucking placental blood so as to feed a collection vessel (the connection is through applying suction on the exterior of an expandable collection bag

which would then translate to suction through the needle). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Deverre with Dracker for the purpose of more efficiently extract blood from the placenta.

With regard to Claims 3-4, Deverre also teaches that the device includes at least one injection or extraction site (8 or 12 in Fig. 2) provided on the tube between said at least one extraction needle (4 or 5) and said collection vessel (1).

With regard to Claim 5, Deverre does not teach that the at least one injection or extraction site is provided on the collection vessel. Dracker teaches an extraction site (where tube 70 connects to collection bag 62, Fig. 3) provided on the collection vessel. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Deverre with Dracker for the purpose of taking blood samples for testing.

With regard to Claim 6, Deverre also teaches that the at least one injection or extraction site (12) is used to inject an anti-coagulant (Col. 3 lines 23-27) or to extract a sample of blood for analysis or to extract the blood contained in said collection vessel.

With regard to Claim 7, Deverre also teaches that the device includes blood-flow control means (13a or 14a).

With regard to Claim 9, Dracker also teaches a collection vessel containing an anti-coagulant before receiving said placental blood (Col. 2 lines 60-63). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Deverre with Dracker for the purpose of properly preserving the blood for future use.

With regard to Claim 17, the method of providing an extraction device, which comprises the structural elements of Claim 1, is obvious over Deverre and Dracker, as

explained above. Deverre also teaches the step of piercing the vein of the umbilical cord or of a placenta (Col. 3 lines 50-51).

5. Claims 2, 11, 12, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deverre in view of Dracker as applied to claim 1 above, and further in view of Seddon et al. (US 6,024,731, "Seddon").

With regard to Claims 2 & 19, Deverre and Dracker do not teach that the suction means comprises a vacuum pump. Seddon teaches that it is conventional to use a medical fluid drainage system with a vacuum pump (Col. 1 line 14) for removal of fluid from the body of a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to employ a known vacuum pump in the combination of Deverre and Dracker for the purpose of facilitating blood removal.

With regard to Claims 11, 12, and 18, Deverre and Dracker do not teach that the suction means comprises a vacuum bottle that simultaneously forms a collection vessel. Seddon uses a Redon type vacuum bottle for removing body fluid from a patient using suction in the Redon bottle. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Deverre and Dracker with Seddon for the purpose of simplifying the placental extraction system (using a Redon bottle allows one to eliminate a separate suction means).

6. Claims 13-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Dracker in view of Seddon.

With regard to Claims 13-15, Dracker teaches a placental-blood extraction device comprising:

an extraction needle for piercing the vein of an umbilical cord or of a placenta,

a collection vessel in fluid connection with the needle via a tube, and

a vacuum.

Dracker does not teach that the vacuum is in fluid connection with the needle so as to feed the collection vessel. Seddon teaches a Redon type collection vessel (Col. 5 lines 1-3) used in a medical setting that creates a vacuum in fluid connection with a tube (see Fig. 1) that is adapted for contacting a wound on a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Dracker with Seddon for the purpose of making the placental-blood extraction device more compact by using a vacuum bottle.

With regard to Claim 16, Dracker does not expressly teach a pump. Seddon teaches a vacuum pump (Col. 1 line 14) used for fluid removal from the body. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Dracker by using a vacuum pump for the purpose of providing a continuous suction on the placenta.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deverre and Dracker as applied to claim 7 above, and further in view of Darling, Jr. (US 6,213,986, "Darling"). Deverre and Seddon do not teach that the blood-flow control means or the suction control means include a knurled adjustment wheel. Darling teaches a fluid-flow control means (10, Fig. 1) that includes a knurled adjustment wheel (110, Figs. 2-3). Furthermore, knurled adjustment wheels are commonly used in everyday life for fluid control, such as faucet knobs. It would have been obvious to one

of ordinary skill in the art at the time of the invention to modify Deverre and Dracker with Darling for the purpose of having a way to control the amount of flow with an easy-to-grip means.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Deverre and Dracker as applied to claim 1 above, and further in view of Van Der Heiden et al. (US 5,879,318, "Van Der Heiden"). Deverre and Dracker do not expressly teach that the device is packaged in sterile manner and is assembled in a single package so as to be ready to use once said package has been opened. Van Der Heiden teaches packaging a cord blood collection device in a sterile manner (Col. 6 lines 15-17) and is assembled in a single package that is ready to use (suggested by Col. 6 lines 35-36 because sterility for the entire closed system can be kept only if the system is already closed before the sterilization process and kept sterilized as a single connected system). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Deverre and Dracker with Van Der Heiden for the purpose of preventing contamination of the device and subsequently the contents inside the device.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 9:00AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/
Examiner, Art Unit 3761
/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761